IN THE UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF PENNSYLVANIA

TRUST UNDER THE WILL OF JAMES WILLS, CITY OF PHILADELPHIA, ACTING BY THE BOARD OF DIRECTORS OF CITY TRUSTS, TRUSTEE,	:	CIVIL ACTION NO. 16-6615
Plaintiff,	:	
v.	:	
SYLVIA MATHEWS BURWELL, SECRETARY, UNITED STATES DEPARTMENT OF HEALTH AND HUMAN SERVICES	:	
Defendant.	:	

M E M O R A N D U M

EDUARDO C. ROBRENO, J. January 25, 2018

Plaintiff Wills Eye Hospital appeals the agency decision denying its application to enroll in Medicare as a hospital. The agency denied the application on the basis that Wills Eye was not sufficiently engaged in providing inpatient care.[1]

Before the Court are the parties' cross-motions for summary judgment on the administrative record. For the reasons

[1] This case was reassigned to the undersigned from Judge O'Neill on August 3, 2017.

discussed below, the Court will **GRANT** the Secretary's Motion for Summary Judgment.[2]

I. BACKGROUND

Medicare, established under Title XVIII of the Social Security Act, 42 U.S.C. § 1395 et seq. (2001), provides a system of federally-funded health insurance for eligible elderly and disabled individuals. Medicare is administered by the Secretary of the Department of Health and Human Services. Heckler v. Ringer, 466 U.S. 602, 605 (1984). The Secretary delegates responsibility for administering the Medicare program to the Centers for Medicare & Medicaid Services Program ("CMS"). See, e.g., Reg'l Med. Transp., Inc. v. Highmark, Inc., No. CIV.A. 04-1969, 2008 WL 936925, at *1 (E.D. Pa. Apr. 2, 2008). Under the Medicare statute, hospitals and other health care providers enter into written provider agreements with the Secretary in order to render services to Medicare beneficiaries and receive reimbursement. § 1395cc.

[2] Also before the Court is the Secretary's Motion for Leave to File a Sur-Reply. See ECF No. 30. Wills Eye opposes this motion. See ECF No. 31. This motion will be **DENIED**, and the Proposed Sur-Reply will not be considered by the Court.

A. Factual Background

The Wills Eye Trust, doing business as Wills Eye Hospital, is a testamentary trust administered by the Commonwealth of Pennsylvania. See Compl. ¶ 12, ECF No. 11. From 2002 to 2006, Wills Eye operated a hospital at 900 Walnut Street in Philadelphia. In 2006, Wills Eye sold its inpatient program at 900 Walnut Street to Thomas Jefferson University Hospital and partnered with Jefferson as an academic affiliate for the provision of inpatient care. Id. at ¶¶ 31-32; Admin. Rec. ("AR") 977. In 2002, Wills Eye created a separate facility at 840 Walnut Street, and that facility began participating in the Medicare program as an Ambulatory Surgical Center. Compl. ¶¶ 31-21. In 2011, Wills Eye renovated the 840 Walnut facility and added four inpatient beds. Id. at ¶¶ 34, 36; AR 3, 14, 40. In 2013, Wills Eye received state licensure of the 840 Walnut Street facility as a hospital from the Pennsylvania Department of Health, and applied for Medicare enrollment as a hospital. AR 14.

To participate in Medicare as a hospital, an entity must enroll in the program by filing an enrollment form; receive approval of a Medicare intermediary; and obtain a hospital license from the state in which it is located. The state licensing agency conducts a survey of all prospective enrollees

to determine, on behalf of CMS, if the applicant satisfies the Medicare Conditions of Participation for hospitals. See 42 C.F.R. §§ 482.11 through 482.58. Additionally, such an applicant must qualify as a "hospital" under section 1861 of the Medicare Act. See 42 C.F.R. § 488.3(a)(1).

The Medicare Act defines "hospital," in relevant part, as an institution that "is primarily engaged in providing, by or under the supervision of physicians, to inpatients (A) diagnostic services and therapeutic services for medical diagnosis, treatment, and care of injured, disabled, or sick persons, or (B) rehabilitation services for the rehabilitation of injured, disabled, or sick persons . . ." . 42 U.S.C. § 1395x(e)(1). Similarly, CMS's regulations provide, in relevant part, that a "qualified hospital" is a facility that "[i]s primarily engaged in providing, by or under the supervision of doctors of medicine or osteopathy, inpatient services for the diagnosis, treatment, and care or rehabilitation of persons who are sick, injured, or disabled . . .". 42 C.F.R. § 409.3.

The parties do not dispute that Wills Eye fulfilled the state licensing requirements as a hospital, and was surveyed and recommended for Medicare enrollment as a hospital by the Medicare intermediary. Pl. Mot. 20, ECF No. 20; Def. Mot. 13-14, ECF No. 22. Even so, CMS denied Wills Eye's application to

enroll in Medicare as a hospital. Pl. Mot. 22, ECF No. 20. CMS based this denial on its determination that Wills Eye was not a "hospital" as defined by § 1395x(e)(1) because it "[was] not primarily engaged in providing inpatient services." Id. at 22.

B. The Administrative Appeals

Wills Eye sought reconsideration and contended, inter alia, that CMS was subjecting it to a new enrollment standard without having first adopted that standard through rulemaking. Pl. Mot. at 22, ECF No. 20. Wills Eye also noted that, according to hospital survey data obtained through the American Hospital Association and the Department of Health, eighty-four percent of hospitals then enrolled in Medicare did not have a "greater inpatient than outpatient volume," and that thirty-seven percent of hospitals participating in Medicare had lower percentages of inpatient care than did Wills Eye. Id. at 23. This data included other specialty eye and ear hospitals that CMS had enrolled in Medicare. Id. Nevertheless, CMS denied Wills Eye's request on reconsideration, reiterating its reasoning and justification. Id.

Then, Wills Eye requested a hearing before an administrative law judge ("ALJ"). At that hearing, Wills Eye contended that it qualified for Medicare enrollment as a

hospital because it met the licensing and other requirements. Pl. Mot. at 24, ECF No. 20. The ALJ sustained CMS's determination. Id. at 25.

Next, Wills Eye requested review of the ALJ's decision by the Health and Human Services Department Appeals Board ("Board") pursuant to 42 C.F.R. §§ 498.5(1)(3), 498.82(a). Pl. Mot. at 24, ECF No. 20. The Board affirmed the ALJ's decision. Id. The Board noted that an institution seeking to enroll in Medicare as a "hospital" must show both that it is "primarily engaged . . . in providing the services" described in § 1861(e)(1), and that it provides those services "primarily to inpatients." AR 29-30, 32-34. The Board declined to endorse "any single numerical test" for comparative volume, concluding that a "hospital" must treat a "significant number of patients" – which it found Wills Eye did not do. AR 15, 33.

In the Board hearing, Wills Eye also argued that, in order to consider relative inpatient-outpatient volume, the Secretary had to formally amend the regulations. AR 34, 35, 48, ECF No. 19. See also 42 U.S.C. § 1395hh(a) (providing that changes to substantive legal standards may not take effect "unless . . . promulgated by . . . regulation"). The Board rejected this argument, concluding that the comparative volume test was not a "change." The Board first reasoned that the

comparative volume factor could be inferred from the general language of § 1861(e)(1) and 42 C.F.R. § 488.3(a)(1). AR 34, 35, 48. Further, the Board indicated that CMS's intent to apply a comparative volume consideration was clear from the Board's prior opinions. See AR 32-34. Wills Eye now seeks judicial review of the agency decision. Before the Court are the parties' cross-motions for summary judgment on the administrative record.[3] On January 11, 2018, the Court heard oral argument from the parties.

II. DISCUSSION

A. Legal Standard

Summary judgment is awarded under Federal Rule of Civil Procedure 56 when "there is no genuine dispute as to any material fact and the movant is entitled to judgment as a matter of law." Fed. R. Civ. P. 56(a); Liberty Mut. Ins. Co. v. Sweeney, 689 F.3d 288, 292 (3d Cir. 2012).

[3] While courts generally prescribe cross-motions for summary judgment as the appropriate mechanism for deciding the legal questions, strictly speaking, not all of the mandates of Federal Rule of Evidence 56(c) are followed. This is because a court does not look for a genuine issue of material fact, but instead only looks as to whether a party is entitled to judgment as a matter of law under the substantive standard provided for judicial review of administrative decisions. The Court will apply this framework as its vehicle for reviewing the administrative decision in this case.

Judicial review of the agency's decision is conducted pursuant to the standards set forth in the Administrative Procedure Act ("APA"), 5 U.S.C. § 706. 42 U.S.C. § 1395oo(f)(1). Under the APA, a court's review is limited to the explanations of the agency in the administrative record. Smith v. Holder, 487 F. App'x 731, 734 (3d Cir. 2012) (citing State Farm., 463 U.S. at 50).

The Court reviews the administrative record taken as a whole. 5 U.S.C. § 706(2)(A),(E). Therefore, the Court reviews the entire agency record, including, as relevant here, the actions of both CMS and the Board. See id. See also Heckler, 466 U.S. at 619 ("[T]he purpose of the exhaustion requirement is to prevent "premature interference with agency processes" and to give the agency a chance "to compile a record which is adequate for judicial review.") (citing Weinberger v. Salfi, 422 U.S. 749, 765 (1975). If, after reviewing the record, the Court is satisfied "that the materials before the Secretary sufficed for a consideration of the relevant factors by [the Secretary] and that there was no clear error of judgment on [the Secretary's] part," then the Court may not disturb the Secretary's decision. C.K. v. New Jersey Dep't of Health & Human Servs., 92 F.3d 171, 183 (3d Cir. 1996) (internal citation omitted).

Accordingly, a court "can set aside the Administrator's decision only if it is 'unsupported by substantial evidence,' is 'arbitrary, capricious, an abuse of discretion, or [is] otherwise not in accordance with law." Albert Einstein Med. Ctr. v. Sebelius, 566 F.3d 368, 372–73 (3d Cir. 2009) (citing Mercy Home Health v. Leavitt, 436 F.3d 370, 377 (3d Cir. 2006). "Substantial evidence is 'more than a mere scintilla. It means such relevant evidence as a reasonable mind might accept as adequate to support a conclusion." Id. (quoting Mercy Home Health, 436 F.3d at 380).

Additionally, a court "must afford substantial deference to an agency's interpretation of its own regulations." Id. at 373 (quoting Mercy Home Health, 436 F.3d. at 377). As the Third Circuit has noted, "[t]his broad deference is particularly appropriate in contexts that involve a 'complex and highly technical regulatory program, such as Medicare, which requires significant expertise and entail[s] the exercise of judgment grounded in policy concerns." Id. (quoting Mercy Home Health, 436 F.3d. at 380). Similarly, the Social Security Act states that "[t]he findings of the [Secretary of Health and Human Services] as to any fact, if supported by substantial evidence shall be conclusive . . .". 42 U.S.C. § 405(g). "In sum, so long as an agency's factfinding is supported by substantial evidence,

reviewing courts lack power to reverse either those findings or the reasonable regulatory interpretations that an agency manifests in the course of making such findings of fact." Id. (quoting Monsour Med. Ctr. v. Heckler, 806 F.2d 1185, 1191 (3d Cir. 1986)).

B. Arbitrary and Capricious Review

The agency action at issue here is the denial of Wills Eye's application to enroll in Medicare as a hospital. Wills Eye argues that this decision was arbitrary and capricious because, in reviewing its application, the Secretary applied a "test" based on its comparative inpatient and outpatient volume. However, CMS did not limit its consideration of Wills Eye's application to any single factor. Instead, noting that the parties did not dispute any of the material facts, it considered "the history, current operations, staffing, location, and other facts and circumstances" regarding Will Eye's facility. AR 3, 27, 43.

For instance, the agency considered that, since 2002, Wills Eye's facility at 840 Walnut Street has participated in the Medicare program as an Ambulatory Surgical Center ("ASC"), see AR 14, which by definition is an entity "that operates exclusively for the purpose of providing surgical services to

patients not requiring hospitalization and in which the expected duration of services would not exceed 24 hours following an admission." 42 C.F.R. § 416.2. Wills Eye performed approximately 8,400 outpatient surgeries per year at the facility, and more than 95% of the procedures during the period from July 2011 to June 2012 were done on an outpatient basis. AR 17, 40-41, 940, 1050.

Then, in 2013, after completing certain renovations and adding four inpatient beds to this facility, Wills Eye applied to change its Medicare participation from an ASC to a hospital. AR 14. In its application, Wills Eye stated that there would be 112 employees, including forty-five registered nurses. AR 40, 995, 1049. However, as the agency noted, Wills Eye did not attempt to show a greater role for inpatient services by proffering any contrary evidence as to the facility's "long focus on ASC services, its inpatient/outpatient ratio, its minimal number of inpatient beds, and its relative staffing," or the facility's square footage, operating costs, or revenues. AR 44.

In its consideration, the agency determined that the statutory requirement that a facility be "primarily engaged" in providing specified services to inpatients "cannot be satisfied when treatment of a significant number of inpatients is not

taking place or when the actual operations do not show inpatient services are the focus of the ongoing business concerns." AR 34. Rather than providing contrary evidence, Wills Eye argued that it should be allowed to receive the higher level of payments that hospitals receive under Medicare for inpatient services, rather than the lower level of payments available under the ASC fee schedule, because of the highly specialized and complex nature of the services that Wills Eye's facility provides. AR 15-16, 50; see also AR 45-46, 50-51. Further, Wills Eye has conceded that "the vast majority of its services do not require inpatient hospitalization." AR 3, 17. Moreover, Wills Eye has not established, or even contended, that CMS had "overlooked some critical factor" as to whether the facility was primarily focused on inpatient care. AR 43, 47. Accordingly, the administrative decision in this case was based on substantial evidence, and it was not arbitrary or capricious.

C. Notice and Comment

Wills Eye contends that, in denying its application to participate in Medicare as a hospital, CMS used a new standard — the purported comparative volume test — for the statutory term "primarily engaged," and that CMS was required to promulgate regulations before it could do so, under both the APA and the Medicare Act. However, the Secretary has not actually adopted

such a "test." Although the Secretary does consider comparative volume, it is only one factor in the evaluation, and is not dispositive. See, e.g., CMS, Survey & Certification Memorandum S&C-08-08, (Jan. 11, 2008), HHS, Final Report to the Congress and Strategic and Implementing Plan Required under Section 5006 of the Deficit Reduction Act of 2005, 79.[4] Moreover, as explained below, the Secretary's consideration of comparative inpatient and outpatient volume is not subject to the notice and comment requirements of either the APA or the Medicare Act.

1. *Notice and Comment under the APA*

The comparative volume factor is, at most, an interpretive rule, for which notice and comment procedures are not required under the APA. Beazer E., Inc. v. EPA, Region III, 963 F.2d 603, 606 (3d Cir. 1992). An interpretive rule seeks only to interpret the meaning already in properly issued regulations, and is meant "to give guidance to [agency] staff and affected parties as to how the agency intends to administer a statute or regulation." Id. at 606. "If the rule in question merely clarifies or explains existing law or regulations, it will be deemed interpretive." Bailey v. Sullivan, 885 F.2d 52, 62 (3d Cir. 1989).

[4] Available at http://www.cms.gov/Medicare/Fraud-and-Abuse/PhysicianSelfReferral/specialty_hospital_issues.html.

Here, the agency interpreted language that was already found in 42 U.S.C. § 1395x(e)(1). Also, the agency did not apply a new mathematical test, or limit its consideration solely to comparative volume numbers or other numerical factors. See AR 39-40, 42-43, 49. Nor did the agency apply a hardline cut-off based on comparative volume numbers. See id. Instead, it considered the comparative volume of Wills Eye's inpatient and outpatient services in the context of (and in addition to) the factual circumstances. See id. Accordingly, the comparative volume test used here was not a substantive rule, and thus not subject to the notice and comment requirement of the APA.

2. *Notice and Comment under the Medicare Act*

Wills Eye also argues that application of the comparative volume consideration violates the notice and comment provision of the Medicare Act. In relevant part, the Medicare Act provides that "[n]o rule, requirement or other statement of policy . . . that establishes or changes a substantive legal standard governing . . . the payment for services . . . shall take effect unless it is promulgated by the Secretary by regulation." 42 U.S.C. § 1395hh(a)(2).[5]

[5] Regulations become final only after the Secretary provides an opportunity for public notice and comment. Id. § 1395hh(b)(1).

However, the Medicare Act's notice and comment requirements for issuing substantive rules do not apply to "manual instructions, interpretive rules, statements of policy, and guidelines of general applicability," which are promulgated pursuant to these provisions and are not published as regulations. Id. § 1395hh(c)(1).[6] As explained above, the comparative volume consideration is a statement of policy, and therefore is an interpretive rule. Because it is an interpretive rule and not a substantive rule, the Medicare Act's notice and comment requirement does not apply.

Also, even if the comparative volume consideration constituted a "rule, requirement, or other statement of policy" governing "the payment of services," it does not "establish[ ] or change[ ] a substantive legal standard." See Id. at § 1395hh(a)(2). A "substantive legal standard" includes a standard that "creates, defines, and regulates the rights, duties, and powers of parties." Allina Health Servs. v. Price, 863 F.3d 937, 943 (D.C. Cir. 2017). The Secretary's determination of whether an entity qualifies as a hospital does effect that entity's legal rights, because the determination controls Medicare

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[6] The Medicare Act thus "places notice-and-comment requirements upon the Secretary for substantive rulemaking similar to those created by the APA." Monmouth Med. Ctr. v. Thompson, 257 F.3d 807, 814 (DC. Cir. 2001) (citing 42 U.S.C. § 1395hh(b); 5 U.S.C. § 553(b)). See also Clarian Health West, LLC v. Hargan, 872 F. 3d 346 (D.C. Cir. 2017).

enrollment. However, this change in legal rights results from the Medicare Act and its implementing regulations – and not from the consideration of comparative inpatient to outpatient volume. See Clarian, 878 F.3d at 355 (holding that the agency decision pursuant to the challenged, published policy "may mean that a hospital receives . . . less in payments. . . But this change in providers' rights results from the Medicare Act and its implementing regulations — not the [challenged policy]").

Put more simply, it is the Medicare Act and its implementing regulations that establish the standard for whether an applicant qualifies as a hospital. The comparative volume consideration does not itself alter the applicable legal standards. Rather, it merely provides CMS and regulated parties, such as Wills Eye, with some form of guidance as to how the legal standards are applied, and the agency maintains the same authority to grant or deny applications as it would without a stated public policy. Accordingly, the comparative volume consideration changes neither the legal standards that govern hospitals, nor the legal standards that govern the Secretary, and thus does not "alter" legal rights. Therefore it is not subject to the notice and comment provision of the Medicare Act.

D. Equal Protection

Wills Eye asserts that CMS applied a comparative volume requirement to it in a discriminatory manner in violation of Equal Protection. Compl. Cts. III, V, VI; Pl. Mot. 41-42. Review of an equal protection claim in the context of agency action is similar to that under the APA. That is, an agency's decision must be upheld if, under the Equal Protection Clause, it can show a "rational basis" for its decision. Nazareth Hosp. v. Sec'y U.S. Dep't of Health & Human Servs., 747 F.3d 172, 180 (3d Cir. 2014) (citing F.C.C. v. Beach Commc'ns, Inc., 508 U.S. 307, 313 (1993)). As such, "the equal protection argument can be folded into the APA argument, since no suspect class is involved and the only question is whether the . . . treatment of [appellees] was rational (i.e., not arbitrary and capricious)." Id. (citing Ursack Inc. v. Sierra Interagency Black Bear Grp., 639 F.3d 949, 955 (9th Cir. 2011)). See also New Jersey Hosp. Ass'n v. Waldman, 73 F.3d 509, 517 (3d Cir. 1995) (finding that arbitrary and capricious review is also governed by whether state can show rational basis). Therefore, the only consideration for the Court is whether the "Secretary set forth a satisfactory, rational explanation" for the agency actions here. Nazareth, 747 F.3d at 180.

The record here shows that the Secretary set forth a rational basis, supported by substantial evidence, for denying Wills Eye's application based on its scanty provision of inpatient services. For example, the Secretary considered Wills Eye's ratio of inpatient to outpatient care, as well as "the history, current operations, staffing, location, and other facts and circumstances" regarding Will Eye's facility. AR 3, 27, 43. Further, because the Secretary applies the comparative volume inquiry as a consideration (rather than as a hardline cut-off) there is no indication of discriminatory selective enforcement, particularly where Wills Eye is a unique facility providing highly specialized services. Wills Eye does not argue (and the record does not support) that CMS rendered its decision as to Wills Eye with discriminatory intent. Accordingly, Wills Eye's Equal Protection claim fails.

E. Fair Notice

Finally, Wills Eye argues that the Secretary's decision violated the Fair Notice doctrine. This claim is based on the premise that the Secretary, in including a comparative inpatient-outpatient ratio consideration, imposed a new standard on Wills Eye.[7] Under the Fair Notice doctrine, which is derived

[7] Wills Eye makes fairness and policy arguments on the effect that the Secretary's decision will have on Wills Eye, as well as other similarly situated entities. Wills Eye emphasized

from the Due Process Clause, a regulated party is entitled to fair notice of the standard with which an agency expects it to conform. See, e.g., FTC v. Wyndham Worldwide Corp., 799 F. 3d 236, 249 (3d Cir. 2015); Fed. Election Comm'n v. Arlen Specter '96, 150 F. Supp. 2d 797, 812 (E.D. Pa. 2001).

The crucial inquiry is whether "[i]f, by reviewing the regulations and other public statements issued by the agency, a regulated party acting in good faith would be able to identify, with 'ascertainable certainty,' the standards with which the agency expects parties to conform." Arlen Specter '96, 150 F. Supp. 2d at 812 (quoting Gen. Elec. Co. v. U.S. E.P.A., 53 F.3d 1324, 1328 (D.C. Cir. 1995)). Notably, adequate notice can come from a variety of publicly-available resources. See Sekula v. FDIC, 39 F.3d 448, 455–57 (3d Cir.1994) (finding sufficient notice where interpretation of ambiguous regulation was consistent with regulation's general principles, and was disseminated to public in layperson's pamphlet). See also Gen. Elec., 53 F.3d at 1329 (stating that notice can come from "regulations and other public statements issued by the agency"); PMD Produce Brokerage Corp. v. U.S. Dept. of Agric., 234 F.3d

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these fairness and policy arguments at oral argument. See ECF No. 38. It is not the province of this Court to second-guess the wisdom of the policies implemented by the Secretary. See, e.g., Motor Vehicle Mfrs. Ass'n of the United States, Inc. v. State Farm Mut. Auto. Ins. Co., 463 U.S. 29, 43 (1983). Such arguments should be addressed, if at all, to the political branches of government.

48, 53 (D.C. Cir. 2000) ("Of course, the Secretary may utilize means other than the language of his Rules of Practice to give adequate notice of his interpretation.").

As noted, Wills Eye argues that it did not have Fair Notice that it would be subject to a comparative inpatient-outpatient volume inquiry. As discussed previously, the comparative volume consideration is not a hardline numerical test, but instead is one consideration in the Secretary's holistic review. The comparative volume consideration was so applied, and explained, in publically-available agency decisions prior to Wills Eye's application at issue here. See Freedom Pain Hosp., DAB No. CR4530 (2016) (H.H.S. Feb. 10, 2016); Kearney Reg'l Med. Ctr., DAB No. 2639 at 12 (2015); Ariz. Surgical Hosp., LLC, DAB No. 1890 at 12 (2003). These decisions made clear that a comparative inpatient-outpatient care ratio was an important factor in whether an applicant was "primarily engaged" in providing services to inpatients. They also made clear that this consideration was not a hardline numerical cutoff test.

In addition to these decisions, the agency has issued other public statements regarding how it determines whether an applicant hospital is "primarily engaged" in proving services to inpatients, also prior to Wills Eye's application. For instance, in 2005, the Secretary publically commented that specialty

hospitals that do not primarily provide care to inpatients do not qualify as hospitals. Specifically, the Secretary stated:

> [S]ome entities providing specialty care may concentrate primarily on outpatient care and thus may not qualify as hospitals. . . . In order to be a hospital, an institution must, among other things, be primarily engaged in furnishing services to inpatients. . . . [A]n institution that currently has a Medicare hospital provider agreement but does not presently meet the requirement of primarily engaging in furnishing services to inpatients would be subject to having its provider agreement terminated pursuant to 42 C.F.R. § 489.53. . . . To address these concerns, we plan to revisit the procedures by which applicant hospitals are examined to insure compliance with relevant standards.

Michael O. Leavitt, Secretary, HHS, Recommendations Regarding Physician- Owned Hospitals, 7.[8] Later that year, the CMS Administrator, explained the agency's intent to examine small surgical hospitals in a hearing before the House Committee on Energy and Commerce. Specifically, the Administrator stated:

> We speculate that these entities may describe themselves as hospitals rather than [ambulatory surgical centers] in part to take advantage of the more favorable payment rates that apply under the hospital outpatient prospective payment system . . . as opposed to the ASC payment system. This is problematic from CMS's perspective, however, since the Medicare program defines a "hospital" as an entity that provides care "primarily" to inpatients. To the extent that such a facility is not, in fact, primarily providing care to inpatients, it is inappropriately categorized as a hospital and should not be treated as one under the Medicare program. . . . CMS will scrutinize whether specialty hospitals meet the definition of a hospital.

[8] Available at https://www.cms.gov/MLNProducts/Downloads/Recommendations_PhysOwnedSpecHosp.pdf.

> Specifically, we will analyze existing data to assess whether specialty hospitals meet the requirements that to be defined as a hospital it must provide primarily inpatient care.

Mark B. McClellan, MD, Ph.D., Administrator, CMS, Testimony Before the House Committee on Energy and Commerce Hearing on Specialty Hospitals: Assessing Their Role in the Delivery of Quality Health Care, May 12, 2005, 2-3.[9] The Administrator declined to lay out a predetermined, hardline metric for whether such an entity would qualify as a hospital, as the Secretary had not adopted such a test. See id.

A year later, the Secretary released an interim report, again stating that there was no hardline test for whether a hospital was "primarily engaged" in providing services to inpatients. The report noted that CMS had "not yet identified any quantitative method, such as percentage of services or ratio of inpatient-to-outpatient services." HHS, Strategic Plan Regarding Physician Investment in Specialty Hospitals Section 5006 of the Deficit Reduction Act Interim Report, (May 9, 2006).[10] The report made clear that the Secretary did not intend to promulgate a formal, hardline definition of "primarily engaged," and that CMS would continue to interpret "primarily

[9] Available at https://www.cms.gov/MLNProducts/Downloads/2-TESTIMONY.pdf.

[10] Available at http://www.cms.gov/Medicare/Fraud-and-Abuse/PhysicianSelfReferral/specialty_hospital_issues.html.

engaged" on a case-by-case, holistic basis. Id. In the subsequent, final report, the Secretary confirmed this. See HHS Final Report, supra at 9.

The Secretary provided yet another public statement noting the case-by-case approach in 2008, in a survey and certification memorandum. See CMS Survey, supra at 1. The memorandum stated that CMS will consider whether a purported hospital "devotes 51% or more of its beds to inpatient care." Id. at 5. Yet, the agency cautioned that "the 51% test may not be dispositive in all cases." Id. It further warned that "we consider the burden of proof (to demonstrate that inpatient care is the primary health care services) to reside with the applicant, and consider that burden to increase substantially as the ratio of inpatient to other beds increases." Id. Accordingly, while the Secretary does consider whether a hospital is providing a majority of its services to inpatients, that numerical consideration is not dispositive. Rather, it is merely one factor considered by CMS, and the agency will consider other relevant and persuasive data, including that presented by the applicant. See id. Such data considered would include "the history, current operations, staffing, location, and other facts and circumstances" regarding the applicant's facility. AR 3, 27, 43; see also CMS Survey, supra at 5.

All of the agency statements discussed here were publically made prior to Wills Eye's application at issue in this case, and thus provided notice. See Sekula, 39 F.3d at 455–57. Accordingly, Wills Eye, acting in good faith, would have been able to determine, with "ascertainable certainty," that the Secretary's review of its application would strongly focus on how much inpatient care Wills Eye provided, and how many inpatient beds Wills Eye had. See Arlen Specter '96, 150 F. Supp. 2d at 812 (quoting Gen. Elec. Co. v. U.S. E.P.A., 53 F.3d 1324, 1328 (D.C. Cir. 1995)).

Further, Wills Eye could similarly have determined that it was much less likely to qualify as a hospital, because its hurdle in proving it was "primarily engaged" in providing care to inpatients would "increase substantially" considering its low "ratio of inpatient to other beds." See CMS Survey, supra at 5. Similarly, Wills Eye was on notice that the agency would also consider factors such as "the history, current operations, staffing, location, and other facts and circumstances," as it did here. AR 3, 27, 43. Therefore, Wills Eye had notice of both the standard for "primarily engaged" and

how it was applied, i.e., holistically and case-by-case. Thus, there was no Fair Notice violation.[11]

III. CONCLUSION

For the reasons stated above, the Court will **GRANT** the Secretary's motion for summary judgment.

An appropriate order follows.

[11] The Fair Notice Doctrine may not even be applicable to this case. See Arkansas Dept. of Human Serv. V. Sebelius, 818 F. Supp. 2d 107, 120-21 (D.D.C. 2011) (noting that a disallowance of federal matching funds provided by CMS to a state for some outpatient hospital services "is categorically different from the kinds of sanctions courts have found sufficiently grave to merit the application of the fair notice doctrine"). However, even assuming that the Fair Notice Doctrine applies, Wills Eye does not meet its requirements here.